510k Summary

General Information

DEC 18 2008

1. **Applicant:**

Genadyne Biotechnologies Inc.
65 Watermill Lane,
Great Neck, NY 11021
(t) 516.487.8787
(f) 516.487.7878
www.genadyne.com

2. **Contact Person:**

Mr. Chien-Ming GOH (Andrew)
Vice President
Genadyne Biotechnologies Inc.
65 Watermill Lane,
Great Neck, NY 11021
Tel: 516-487-8787
Fax: 516-487-7878
Andrew@genadyne.com

3. **Trade/Proprietary Name Including Model Number of Device:**

   Genadyne A4 Wound Vacuum System

4. **Common Name or Classification Name (21 CFR Part 807.87) of Device:**

   Powered Suction Pump (21 CFR 878.4780, Product Code BTA)

5. **Class in which Device has been placed:**

   Class II

6. **Reason for Premarket Notification:**

   Introduction of a new device that is substantially equivalent to a legally marketed device.

7. **Identification of Legally Marketed Device Which We Claim Substantial Equivalence (Predicate Device):**

   BlueSky VISTA™ Wound Vacuum System, K061367 (Aug 10, 2006)

8. Compliance with Requirements of the Federal FD&C Act:

The General and Restorative Device Panel (DGRD) has classified this device as Class II, 21 CFR 878.4780

Product Code: BTA

9. Kit Certification and Information:

This device kit has been tested and is substantially equivalent to the kit of the predicate device.

Please refer to Attachment E for the performance testing on the dressing kit for both the Genadyne A4 Wound Vacuum System and the predicate device. Please do refer to Attachment F for the kit information and material data safety sheets for each component of the dressing kit.

10. Description of the Device

The product is a portable suction device that may promote wound healing when used with accessory wound sealing kits.

11. Intended use of the Device

The Genadyne A4 Wound Vacuum System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

12. Substantial Equivalence

In establishing substantial equivalence to the predicate device, Genadyne Biotechnologies evaluated the indications for use, material, technology, product specifications, and energy requirements of the system. Performance testing has been completed to demonstrate the safe and effective use of the Genadyne A4 Wound Vacuum System for the intended use.

13. Summary of Safety and Effectiveness

Performance testing and device comparison demonstrates that the subject device is substantially equivalent to the predicate device, and is safe and effective for the intended use.

14. Comparison to Predicate Device

Table of Comparison to Legally Marketed Device:

Comparative Information		
	New Device	**Predicate Device**
Company	Genadyne Biotechnologies	BlueSky Medical Group, Inc.
Device Name	A4 Wound Vacuum System	BlueSky VISTA™ Wound Vacuum System
510 (K) Number	K082676	K061367
Technical Data		
Suction Capacity	5 liters per minute	8 liters per minute
Max Vacuum	230 mmHg	200 mmHg
Power Requirements	24 VDC, 1A	100-240 V AC, 60 Hz
Battery Type	Ni-MH	Ni-MH
Dimensions and Weight	200 x 180 x 80 mm / 1.36 Kg	260 x 250 x 106 mm / 1.9 Kg
Accessories		
Canisters	800 ml disposable canister with a build-in hydrophobic shut off filter for overflow protection	250 ml or 800 ml disposable canister
Reusable	Yes	Yes
Sterile	Non Sterile	Non Sterile
Accessory Kit		
	A4 Wound Sealing Kit which is based on the teachings of Dr. Mark Chariker and Dr. Katherine Jeter[1], which includes:	BlueSky Medical Wound Sealing Kits, which includes:
-	Non-adherent gauze	Non-adherent gauze
-	Anti-Microbial gauze	Anti-Microbial gauze
-	Transparent film dressing	Transparent film dressing
-	Silicone flat drain	Silicone flat drain

[1] Chariker ME, Jeter KF, Tintle TE. Effective management of incisional and cutaneous fistulae with closed suction wound drainage. *Contemporary Surg.* 1989;(34):59-63.

Indications for Use		
	The Genadyne A4 Wound Vacuum System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.	The BlueSky VISTA™ Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing.
Contraindications		
	The Genadyne A4 is contraindicated in the presence of :	The VISTA™ is contraindicated in the presence of:
-	Necrotic tissue	Necrotic tissue
-	Untreated osteomyelitis	Untreated osteomyelitis
-	Malignancy (with exception to enhance quality of life)	Malignancy (with exception to enhance quality of life)
-	Untreated malnutrition	Untreated malnutrition
-	Exposed arteries, veins, or organs	Exposed arteries, veins, or organs
Precautions		
	Precautions should be taken for patients who are or may be:	Precautions should be taken for patients who are or may be:
-	Receiving anticoagulant therapy	Receiving anticoagulant therapy
-	Suffering from difficult hemostasis	Suffering from difficult hemostasis
-	Untreated for malnutrition	Untreated for malnutrition
-	Non-complaint or combative	Non-complaint or combative
Compliance		
	UL 60601-1	UL 60601-1
	CAN/CSA C22.2 No. 601-1-M90	IEC 0601-1-2
		CAN/CSA C22.2 No. 601.1
Storage / Transport		
	-18°C to +43°C (0°F to 110°F)	-30 to +50° C (-22 to 122° F)
	Relative Humidity 10% to 95 %	5 to 90% Humidity, non condensing
	700 - 1060 mbar Atmospheric	700 – 1060 mbar Atmospheric

	pressure	pressure
Operation	18°C to 34°C (65°F to 94°F)	+5 to +35° C (41 to 95° F)
	Relative Humidity 10% to 95 %	20 to 80 % Humidity, non condensing
	700 - 1060 mbar Atmospheric pressure	700 – 1060 mbar Atmospheric pressure
Testing		
	IEC 60601-1-2	-
	FCC part 15 Class B	-
	EN 55011	-
	IEC 61000-4-2	-
	IEC 61000-4-3	-

15. Comparative Performance Evaluation:

The FDA Decision Tree for substantial equivalence was followed and the steps involved have been considered. The rationale for each step is discussed below. For reviewer convenience, the numbering system used by FDA on the decision tree has been followed by Genadyne in their process for the substantial equivalence determination rationale.

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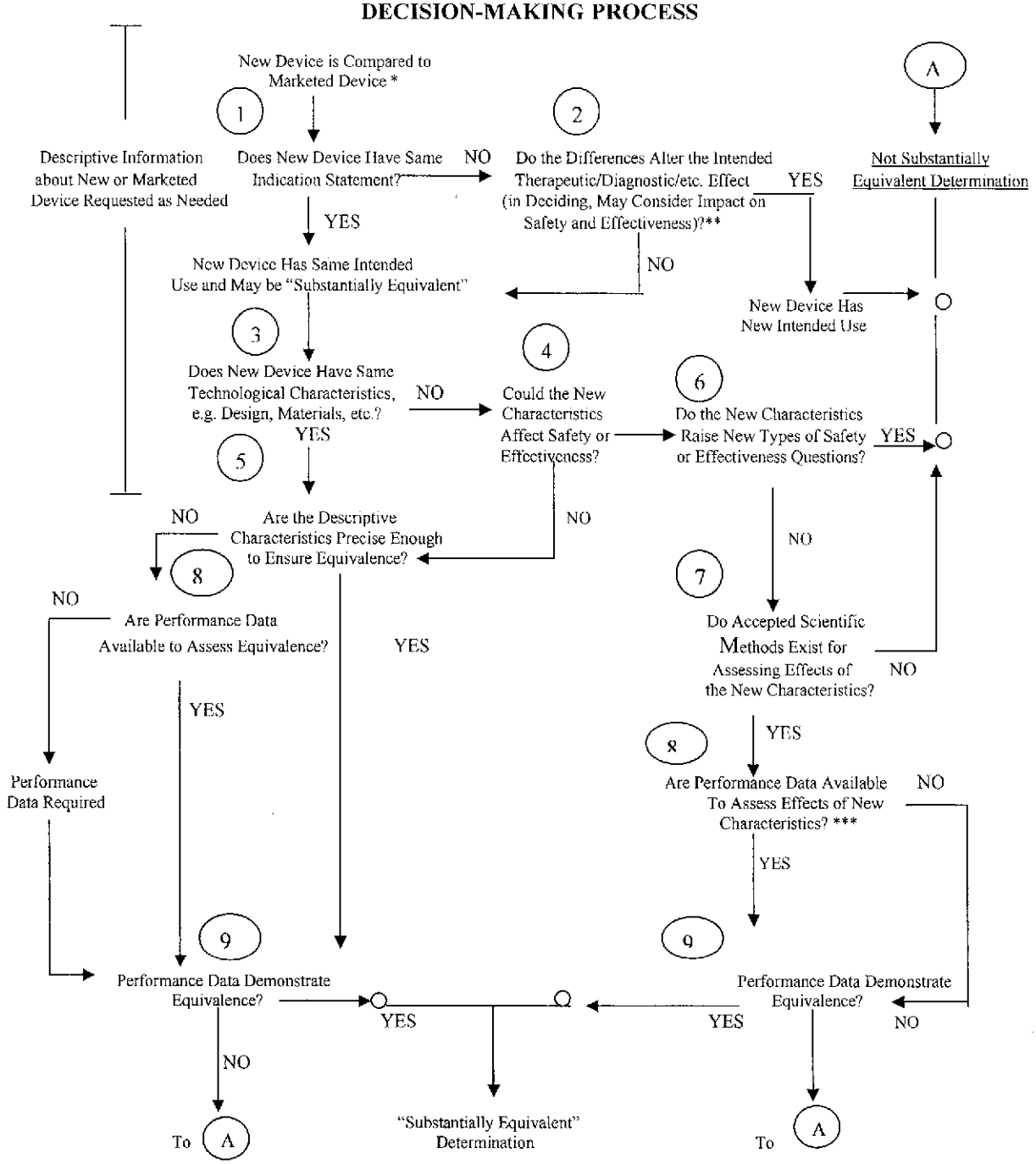
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

16. Discussion of Substantial Equivalence:

Note 1: Does new device have same indication statement as the predicate device(s)?

Yes. The Genadyne A4 Wound Vacuum System and the BlueSky VISTA™ Wound Vacuum System are both indicated for patients who would benefit from a suction device particularly as the device may promote wound healing.

Note 3: Does the device have the same technological characteristics, e.g., design, materials, etc.?

Yes. The Genadyne A4 Wound Vacuum System is design with a suction pump, can be externally and internally powered and has a collection canister, same as the BlueSky VISTA™ Wound Vacuum System, which also features a suction pump, a collection canister and can be powered externally and internally.

Note 5: Are the descriptive characteristics precise enough to ensure equivalence?

Yes. The characteristics of the Genadyne A4 Wound Vacuum System and the BlueSky VISTA™ Wound Vacuum System are precise enough to ensure equivalence, based on the table in item 14 in the 510K Summary.

17. Discussion of Similarities and Differences

Device Similarities

Indication for use

The indication for use is identical for the Genadyne A4 Wound Vacuum System and the predicate device.

Configuration

All devices are sold non-sterile and are intended to be reusable. Devices are compatible with off-the-shelf accessories, such as disposable 800ml canisters.

Basic Product Function

The Genadyne A4 Wound Vacuum System and the predicate device have the same product function of generating a vacuum to provide general use suction and collection of liquids into an off-the-shelf canister reservoir which may promote wound healing for patient who would benefit from it.

Device Differences

In comparison to the predicate devices, the Genadyne A4 Powered Wound Vacuum System has several differences which do not affect the device safety and effectiveness of the Genadyne A4 Wound Vacuum System. These differences between the Genadyne A4 Wound Vacuum System and the predicate device are described in further detail below.

BlueSky VISTA™ Wound Vacuum System

The differences between the Genadyne A4 Wound Vacuum System and the BlueSky VISTA™ Wound Vacuum System are that the Genadyne A4 Wound Vacuum System is lighter in weight and has a longer battery life. In all other aspects, the Genadyne A4 Wound Vacuum System and the predicate device is substantially equivalent.

18. Conclusions:

Genadyne believes the Genadyne A4 Wound Vacuum System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

Genadyne Biotechnologies, Inc.
% Mr. Chien-Ming Goh
65 Watermill Lane
Great Neck, New York 11021

Re: K082676
Trade/Device Name: Genadyne A4 Wound Vacuum System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: November 12, 2008
Received: November 14, 2008

Dear Mr. Goh:

This letter corrects our substantially equivalent letter of December 18, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Daf D.a

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082676

Indications for Use

510(k) Number (if known):

Device Name: Genadyne A4 Wound Vacuum System

Indications For Use:

The Genadyne A4 Wound Vacuum System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

Prescription Use ___X__ **OR** **Over-The Counter Use_____**
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082676